GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2613
ANSWERED ON:17.03.2017
Fixed Dose Combination Medicines
Galla Shri Jayadev

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

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(a) whether 344 fixed dose combination medicines have been banned by the Hon'ble High Court of Delhi;

(b) if so, the details thereof and the reaction of the Government thereto;

(c) the details of WHO guidelines in this regard;

(d) whether the said norms are followed in this context; and

(e) if so the details thereof and if not the reasons therefor?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): The Government vide Gazette Notifications dated 10.03.2016 prohibited manufacture for sale, sale and distribution for human use, 344 Fixed Dose Combinations (FDCs) in public interest as these FDCs were likely to involve risk to human beings and safer alternatives were available. The notifications were issued after a detailed scientific assessment and examination of all pertinent issues. However many manufacturers filed a number of cases in different High Courts. The Hon'ble High Court of Delhi has quashed these notifications vide its Judgment dated 01.12.2016. The Government has challenged the Judgement of High Court of Delhi before the Hon''ble Supreme Court of India.
(c) to (e): WHO issues guidelines for registration of Fixed Dose Combination medicinal products. However, manufacture, import, sale and distribution of Fixed Dose Combination drugs in the country are regulated as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder.
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